

1615

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: A.G. DAFTOTIS et al.

Serial No. 09/445,837

Filed: December 13, 1999

For: METHOD FOR INHIBITING BONE  
RESORPTION

B-IDS

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Art Unit: 1615

Examiner: T.J. Criares

Assistant Commissioner for Patents  
Washington, D.C. 20231

<sup>SUPPLEMENTAL</sup>  
INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application.

This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

MERCK &amp; CO., INC.

By John D. Ri Date 6/14/02



## INFORMATION DISCLOSURE STATEMENT

4. Copies of the references listed on the attached form are not enclosed because they have been submitted to or cited by the Office in a related application as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE
09/388,659	September 2, 1999	20002YIB

upon which the instant application relies for an earlier filing date under 35 U.S.C. 120. Therefore, pursuant to 37 C.F.R. 1.98(d), copies of these references are not enclosed herewith. If this is inconvenient, additional copies will be submitted upon request.

## 5. In accordance with 37 C.F.R. 1.97, (check one)

the attached information is filed within three months of the filing date of the captioned case.

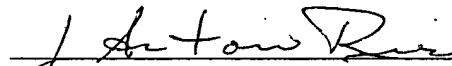
the attached information is filed more than three months after the filing date but prior to a first Official Action on the merits.

the attached information is being filed more than three months after the filing date and after receipt of the first Office Action on the merits, but before Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).

the undersigned certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.

the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of the statement.

Respectfully submitted,

  
By: J. Antonio Garcia-Rivas  
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Date: June 14, 2002

<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE</b></p> <p><b>STATEMENT BY APPLICANT</b></p> <p><i>JUN 25 2002</i></p> <p>(use <b>any</b> <b>TRADEMARK</b> <b>OFFICE</b> <b>as necessary</b>)</p>				<p>COMPLETE IF KNOWN</p> <p>Application Number 09/445,837</p> <p>Filing Date December 13, 1999</p> <p>First Named Inventor A.G. Daifotis</p> <p>Group Art Unit 1615</p> <p>Examiner Name T.J. Criares</p>	
Sheet	1	of	3	Attorney Docket Number	20002YP

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

Examiner Signature \_\_\_\_\_ Date Considered \_\_\_\_\_

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Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc. 10/05/2001

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

JUN 25 2002

(use as many sheets as necessary)

Sheet

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of

3

## COMPLETE IF KNOWN

Application Number	09/445,837
Filing Date	December 13, 1999
First Named Inventor	A.G. Daifotis
Group Art Unit	1615
Examiner Name	T.J. Criares

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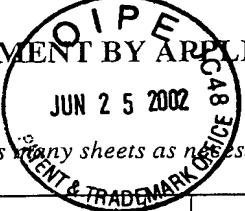
## OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AA	Lunar News (July 1996), "Update: Bisphosphonate", pp. 23-24
	AB	Lunar News (April 1996), "Update: Bisphosphonate", p. 31
	AC	The Pink Sheet (Dec. 18, 1995), Vol. 57, Issue 51, "Merck Cozaar generating 25,000 scripts weekly after six months on market; Fosamax off to quick start, company tells securities analyst meeting"
	AD	Scrip (11/24/99), "Merck develops once-weekly Fosamax"
	AE	Baran, Geriatrics, Vol. 56, No. 3 (March 2001), pp. 28-32, "Osteoporosis: Efficacy and safety of a bisphosphonate dosed once weekly"
	AF	Bone et al., Clinical Therapeutics, Vol. 22, No. 1 (2000), pp. 15-28, "Weekly administration of alendronate: Rationale and plan for clinical assessment"
	AG	Fleisch, Expert Opinion Therapeutic Patents, Vol. 11, No. 9 (2000), p. 1371-1381, "Bisphosphonates: mechanisms of action"
	AH	Peter et al., Journal of Pharmacology & Experimental Therapeutics, Vol. 276, No. 1 (1996), p. 271-276, "Long-term safety of the aminobisphosphonate alendronate in adult dogs"
	AI	Rodan et al., Osteoporosis International (1993) Suppl., 3:S7-12, "Preclinical pharmacology of alendronate"
	AJ	Schnitzer, Expert Opinion Pharmacother., Vol. 2, No. 9 (2001), pp. 1461-1472, "Update on alendronate for osteoporosis: once-weekly dosing"
	AK	Schnitzer et al., Aging: Clinical and Experimental Research, Vol. 12, No. 1 (2000), p. 1-12, "Therapeutic equivalence of alendronate 70 mg once-weekly and alendronate 10 mg daily in the treatment of osteoporosis"
	AL	Seedor et al., Journal of Bone & Mineral Research, Vol. 6, No. 4 (1991), pp. 339-346, "The bisphosphonate alendronate (MK-217) inhibits bone loss due to ovariectomy in rats"
	AM	Sorrentino, Endoscopy, Vol. 28 (1996), p. 529, "Esophageal ulceration due to alendronate"
	AN	Blank, American College of Gastroenterology 66th Annual Scientific Meeting, "Lack of gastric adaptation to weekly versus daily alendronate administration in rats"
	AO	Bone et al., Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), M392, "Once-weekly alendronate: Two year subgroup efficacy analyses in postmenopausal women with osteoporosis"

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<p>Substitute for form 1449A/PTO <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> <b>JUN 25 2002</b> <i>(use as many sheets as necessary)</i>  Sheet <b>3</b> of <b>3</b></p>		<b>COMPLETE IF KNOWN</b>	
		Application Number	09/445,837
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		Group Art Unit	1615
		Examiner Name	T.J. Criares
Attorney Docket Number <b>20002YP</b>			

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<b>OTHER NON PATENT LITERATURE DOCUMENTS</b>		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
AP		Bone III et al., 6th International Symposium on Clinical Disorders of Bone and Mineral Metabolism, Venice, Italy, November 20-25, 1999, "Alendronate 70 mg once weekly is therapeutically equivalent to alendronate in 10 mg daily"
AQ		Brown et al., Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), M402, "Efficacy, safety and tolerability of once weekly (80 mg vs. 160 mg) oral alendronate in postmenopausal osteoporosis"
AR		Delaney et al., ENDO 2001, The Endocrine Society's 83rd Annual Meeting, Denver, Colorado (June 2001), Abstract, P1-469 (June 2001), p. 249, "Bone density changes in response to risedronate once weekly"
AS		Gordon et al., ENDO 2001, The Endocrine Society's 83rd Annual Meeting, Denver, Colorado (June 2001), Abstract, P1-460 (June 2001), p. 247, "Weekly administration of risedronate increase bone mineral density"
AT		Lindsay et al., Arthritis & Rheumatism, Vo. 44, No. 9 (Suppl.), Abstract No. 604, "Risedronate 35 mg once a week is as effective as 5 mg daily in postmenopausal women"
AU		Rizzoli et al., Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), M401, "Two year results of once-weekly administration of alendronate 70 mg for the treatment of postmenopausal osteoporosis"
AV		Rizzoli et al., Annals of the Rheumatic Diseases, Annual European Congress of Rheumatology, EULAR 2001, Prague, Czech Republic, Vol. 60, Suppl. 1 (July 2001), Abstract SAT0164, p. 256, "Two year results of once-weekly administration of alendronate 70 mg for the treatment of postmenopausal osteoporosis"
AW		Van Dyke, et al., Annals of the Rheumatic Diseases, Annual European Congress of Rheumatology, EULAR 2001, Prague, Czech Republic, Vol. 60, Suppl. 1 (July 2001), Abstract SAT0167, p. 256, "Safety of once-weekly alendronate 70 mg in periodontal disease"
AX		Wimalawansa, Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), Abstract SA352, "Once a week alendronate therapy: A convenient and effective way of prevention and treatment of osteoporosis: A four-year clinical study"
AY		Wimalawansa, Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), Abstract SU399, "Efficacy of once a week risedronate in comparison with once-weekly alendronate therapy for postmenopausal osteoporosis: One-year data"
AZ		Wimalawansa, ENDO 2001, The Endocrine Society's 83rd Annual Meeting, Denver, Colorado (June 2001), Abstract P1-438, p. 241-242, "Highly efficacious and cost-effective alendronate regimen for postmenopausal osteoporosis: A four-year clinical study"
BA		Woodson, Osteoporosis International, Vol. 11, Suppl. 2 (2000), Chicago, Illinois, p. S204, Abstract 550 (514), "Once weekly risedronate therapy"

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